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9/24/02PATENTS  
Attorney Docket No. 25352-0029  
OFFICIAL COMMUNICATION

## CERTIFICATE OF FACSIMILE TRANSMISSION

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9/18/02  
Date

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Prasad V.V.S.V. Manchern et al.

: Confirmation No.: 1824

App. No.: 09/977,059

: Art Unit: 1617

Filed: April 2, 2002

: Examiner: Mojdeh Bahar

For: Insulin receptor activators for the treatment of metabolic disorders induced by treatment with  
HIV protease inhibitors

Commissioner for Patents  
Washington, DC 20231

Sir:

## RESPONSE TO OFFICE ACTION

In response to the Office Action mailed September 10, 2002, please enter the following  
response to restriction requirement and election of species and consider the following remarks.

## The restriction requirement

Claims 1 - 20 were subject to a restriction requirement, described as being between:

- I. Claims 1-5, 18-20 drawn to a method of treating a metabolic disorder in a person induced by treatment with an HIV protease inhibitor employing a compound of formula I.
- II. Claim 6 drawn to [the same method using] a compound of formula II.
- III. Claim 7 drawn to [the same method using] a compound of formula III.
- IV. Claim 8 drawn to [the same method using] a compound of formula IV.
- V. Claim 9 drawn to [the same method using] a compound of formula V.
- VI. Claim 10 drawn to [the same method using] a compound of formula VI.
- VII. Claim 11 drawn to [the same method using] a compound of formula VII.
- VIII. Claims 12-16 drawn to [the same method using] a compound of formula I and another active ingredient for treating insulin resistance.
- IX. Claim 17 drawn to [the same method using] two compounds of formulae I - VII."

with the Examiner asserting that the inventions are unrelated because they "have different modes of operation."

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Applicants submit that the restriction requirement so written is improper, both because it improperly groups the claims and because it fails to acknowledge the existence of linking/generic claims, and it is traversed on those grounds.

Claims 1 and 2 are not drawn to the method using a compound of formula I, but are generic to any insulin receptor-activating compound.

Claims 12 - 16 are not drawn to the method using a compound of formula I and an additional form of treatment, but are generic to any insulin receptor-activating compound and an additional form of treatment. Claim 17, though drawn to the method using two compounds of formulae I - VII as described by the Examiner, is in effect a claim that is subgeneric to claim 12.

Claim 19 is a claim to the method using a specific compound of formula VII, not formula I.

In the interest of expediting prosecution, Applicants offer what they consider to be a proper regrouping of the claims and an election consonant with that regrouping.

Applicants submit that a proper regrouping of the claims would be:

Linking/Generic:

Claims 1 and 2 drawn to a method of treating a metabolic disorder in a person induced by treatment with an HIV protease inhibitor using an insulin receptor-activating compound.

Linking/Subgeneric but not to compounds (except claim 17):

Claims 12 - 17 drawn to the method using an insulin receptor-activating compound and another active ingredient for treating insulin resistance.

Subgeneric to compounds (species):

- A. Claims 3 - 5, 18, and 20 drawn to the method using a compound of formula I.
- B. Claim 6 drawn to the method using a compound of formula II.
- C. Claim 7 drawn to the method using a compound of formula III.
- D. Claim 8 drawn to the method using a compound of formula IV.
- E. Claim 9 drawn to the method using a compound of formula V.
- F. Claim 10 drawn to the method using a compound of formula VI.
- G. Claims 11 and 19 drawn to the method using a compound of formula VII.

Applicants accept for the purposes of restriction that the methods using the compounds of formulae I - VII are independent and distinct (though Applicants disagree with the Examiner's statement that the different species have different modes of operation, since the different species are all disclosed as being insulin receptor-activating compounds and therefore possess a common mode of operation), and that in the absence of linking claims restriction may be required therebetween. But that is not the case here, and claims 1 and 2, at least, are linking claims linking the species A - G. Claims 12 - 17, though requiring the use of two active ingredients, one at least being an insulin receptor-activating compound, are also linking claims.

Applicants submit that, with the claims properly regrouped, the restriction requirement is governed by 37 CFR 1.146 and the practice under MPEP 809 - 809.04.

Applicants elect for examination subgenus A, the subgenus where the method uses a compound of formula I. This election is made without traverse, subject of course to the provisions regarding linking claims where, if the linking claims are found allowable, the nonelected subgenera must also be examined. Claims reading on that subgenus are claims 1 - 5, 12 - 18, and 20.

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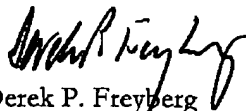
The Examiner has made a further requirement for an election of a specific compound within the compounds of formulae I - VII.

Within subgenus A, applicants elect for examination the method where the specific compound of formula I is the compound whose use is claimed in claim 18. This election is made without traverse, subject of course to the provisions regarding linking claims where, if the linking claims are found allowable, the nonelected species must also be examined. Claims reading on that species are claims 1 - 5 and 12 - 18.

#### Information Disclosure

Applicants note that the Examiner of this application is the Examiner of its continuation-in-part, Application No. 10/115,595. In the first Office Action on that application, the Examiner cited the abstract (from *Entrez-PubMed*) of Yarasheski et al., "Insulin resistance in HIV protease-inhibitor-associated diabetes", *J. Acquir. Immune Defic. Syndr.*, **21**, 209-216 (1999); and Applicants in their response provided a copy of the full article and a copy of Horn, "Postcard from Athens: Insulin resistance and more at the 3rd international workshop on lipodystrophy and adverse drug events in HIV", *The PRN Notebook*<sup>TM</sup>, 6(4), 28-31 (2001). Although the Examiner is believed well aware of these documents, for the sake of completeness, Applicants cite them in this application and enclose copies thereof.

Respectfully submitted,



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